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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,656	02/14/2000	William E. Baumzweiger	50065	6960

7590 08/11/2005

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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09/503,656			

EXAMINER

ART UNIT	PAPER
	20050729

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Pursuant to the Petition Decision dated July 12, 2005, wherein Applicant's petition to withdraw abandonment of Application 09/503,656 was granted, the attached Office Action, originally mailed July 06, 2004, is resent.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

5.00

Office Action Summary	Application No.	Applicant(s)	
	09/503,656	BAUMZWEIGER ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed October 28, 2003 has been received and entered into the file.

Applicant's arguments filed October 28, 2003 have been fully considered but they are not deemed to be persuasive.

Applicant's statement regarding those claims presented are incorrect. Applicants aver claims 86-94 are resented, yet claims numbered 86-104 are presented.

Claims 86-104 are presented for examination.

Applicant's election with traverse of group II, claim 5 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that are not set forth . This is not found persuasive because traversal must factually based. Absent an identifiable reason for traversal, objections to the restriction are unconvincing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 86-104 will be examiner to the extent they read on the elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither those disorders of the central nervous system possessing those symptomologies herein envisioned , nor those therapeutic agents to be employed " that block calcium intake channels on body cells", "substantially like nimodipine and felodipine", "aid in the inhibition of neural activity in the brain, substantially like gabatril and tigabine, together with and anti-epileptic drug to

increase sensitivity of receptor neuron complexes"", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", or acts "to relieves at least one symptom of psychosis". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these conditions, or compounds required to provide therapy for these conditions without undue experimentation. In the instant case, only a limited number of disorders of the central nervous system are recited; additionally, scant guidance as to those agents useful to "block calcium intake channels on body cells (2)"', "aid in the inhibition of neural activity in the brain(1)", "provides immune system equilibrium(2)", "inhibits body actions that lead to blood clotting(1)", "acts as a chelating agent"(1), or acts "to relieves at least one symptom of psychosis(1)" examples are set forth, thereby failing to provide sufficient working examples. Examiner notes Applicants claim all antiviral, antifungal and antibiotic drugs, for treating any disorder of the central nervous system, yet recite in the specification recite 2 antiviral compounds, 2 antifungal compounds and no antibiotic compounds. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all disorders of the central nervous system, save cancer, all therapeutic agents "that block calcium intake channels on body cells ', "aid in the inhibition of neural activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis", an antiviral compound, an antifungal compound, or an antibiotic,

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 86-104 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 86-104 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 86-104 are rendered indefinite by the phrases "a disorder of the central nervous system" possessing those symptoms herein envisioned, drugs "that block calcium intake channels on body cells ', "aid in the inhibition of neural activity in the brain" "substantially like nimodipine and felodipine", "substantially like gabatril and tigabine, together with and anti-epileptic drug to increase sensitivity of receptor neuron complexes", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" , an antiviral compound, an antifungal compound, or an antibiotic, and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining diseases which are "a disorder of the central nervous system", or drugs "that block calcium intake channels on body cells ', "aid in the inhibition of neural activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" , an antiviral compound, an antifungal compound, or an

antibiotic are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's terms fail to clearly define the subject matter encompassed by the instant claims, thus are properly rejected under 35 USC 112, second paragraph.

connected, to make or use the invention commensurate in scope with these claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104 are rejected under 35 U.S.C. § 102(b) as being anticipated by Baumzweiger (3).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104 are rejected under 35 U.S.C. § 103 as being unpatentable over Baumzweiger (4) and Baumzweiger (3).

Baumzweiger (4) teaches the Gulf War Syndrome (GWS) as a "Brainstem-Limbic" disorder possessing those symptomologies herein envisioned. Baumzweiger (3) teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in dosage forms. Taught by Baumzweiger (3), at pages 5-8, as useful concomitantly for treatment of "Gulf War Syndrome" are various calcium channel blockers, gabatil, as useful for treating "a disorder of the central nervous system ", and thus useful as an anti-epileptic compound, or a useful "aid in the inhibition of neural activity in the brain", celebrex, as an agent that "provides immune system equilibrium", EDTA, as a compound that "inhibits body actions that lead to blood clotting", or "acts as a chelating agent", with klonapin, acting "to relieves at least one symptom of psychosis" ,AZT, as an antiviral compound, 0zithromax, as an antibiotic, vitamin C, to deal with oxidative stress, and provides direction to the skilled artisan in the diagnosis of this malady and outlines these compounds use for providing treatment. Additionally, Baumzweiger teaches oxidative stress as integral to GWS,

renders obvious the use of oxidative compounds to therapy of such conditions (see pages 3-5). These medicament are taught as useful for treating gulf war syndrome, viewed by the skilled artisan as indistinguishable from those conditions herein claimed. Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104, and the primary reference, differ as to:

1) the concomitant employment of these medicaments,

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional therapeutic agents, taught by the cited prior art as useful for the same purpose. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Examiner sees those maladies herein claimed and those recited previously as indistinguishable. Additionally, Examiner notes Baumzweiger (3) and Baumzweiger (4) publication dates are listed in the body of the text, and on the presented 1449, both being published in 1998. Examiner notes the instant Application's filing date of February 14, 2000. Absent information to the contrary, these publications would be

published more than a year prior to the instant filing date, hence anticipatory, and obviating.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Those recitations of function fail inform the skilled artisan as to the instant claims metes and bounds, thereby failing to meet Applicants' burden under 35 USC 12, second paragraph.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number

is 703-308-4603. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0631.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617